Conceptions
Women's Health and Fertility Specialists, P.C.

Bruce H. Albrecht, M.D.
Elene Strates, M.D.
Richard J. Worley, M.D.

7720 South Broadway, Suite 580
Littleton, Colorado 80122-2624
303-794-0045 Fax: 303-794-2054

1000 Alpine, Suite 110
Boulder, Colorado 80304-3409
303-449-1084 Fax: 303-449-1039

4600 Hale Pkwy., Suite 420
Denver, Colorado 80220-4000
303-399-6515 Fax: 303-399-2284

December 17, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5360 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket #97N-484S Suitability Determination for
Donors for Human Cellular and Tissue-based Products

To Whom It May Concern:

It has come to my attention in reading the above proposed rules regarding donation of human tissue that the section regarding donor egg IVF is not only unacceptable it is highly objectionable and is likely to make the use of donor eggs either impossible for most in vitro fertilization clinics to provide to their patients, or so expensive that only the very rich and elite will be able to afford this technology. Donor egg cycles are already extremely expensive and adding a quarantine of the donor eggs, or of the embryos that result from the donor eggs would be an unreasonable hardship to place on the recipient patients.

There is no evidence that oocytes, embryos, or for that matter, isolated sperm cells that are used for in vitro fertilization are vectors of any disease process including the diseases listed in your proposal. Sexually transmitted diseases and other infectious diseases are not passed by in vitro fertilization. There has not been one case report of any infectious disease being passed by this technology. In vitro fertilization has been utilized successfully for over twenty-one years with a very large number of pregnancies that have been reported, and no sexually transmitted diseases or other infectious diseases including HIV have been contracted during that time.

Quarantining embryos will significantly increase costs of an individual cycle of treatment. However, what is even more unacceptable is that the success rate with freezing drops significantly. The success rate of in vitro fertilization using frozen embryos is less than half the success rate with fresh embryos. On this basis alone the cost would be more than doubled in order to obtain the same number of pregnancies. If a quarantine of eggs is utilized the success rate drops even further. The success rate of frozen eggs is so poor that it is not utilized at all in the process of in vitro fertilization. We would anticipate that this would have the effect of increasing the cost of a pregnancy from donor eggs by more than tenfold. With the costs already approximately $15,000, this would put donor egg utilization out of the realm of all but a very few number of patients.

More importantly, there are many embryos, which if used fresh, would have a high likelihood of becoming a human life that would be lost by the freezing of embryos. These unnecessary deaths of embryos are unconscionable given the tremendous efforts, both emotionally, financially, and personally, that patients make to try to bring a wanted child into this world.

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Lastly, but certainly one of the most important issues, is the immeasurable anxiety and frustration that would be dramatically increased in fertility patients who have to delay the utilization of the embryos while waiting for this quarantine. There is no price tag that one can put on the emotional suffering that this group of patients go through and to increase that suffering for no scientific or medical purposes, but merely to satisfy a bureaucratic protocol is cruel. It seems as though the proposed rules are merely an extension of the rules that are used with donor semen which carries with it a much different risk for transmission of disease and one that is not just hypothetical but has been observed and reported many times.

In summary, it is my feeling that the FDA is attempting to interfere with the practice of medicine and the relationship between patients and physicians foisting unnecessary bureaucratic restrictions on the use of donor-egg IVF. With no scientific justification for these protocols I asked that this decision be seriously reconsidered to avoid the unnecessary increase in costs, decrease in success rates, death of embryos, and delay in childbirth in an already older patient.

Sincerely,

Richard J. Worley, M.D.

RJW/mah

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